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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	**PAPER NUMBER**
1634	15

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/332,659	Zenhausern
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- *If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.*
- *If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.*
- *Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).*
- *Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).*

Status

1) ☒ *Responsive to communication(s) filed on Oct 25, 2002 .*

2a) ☐ *This action is* **FINAL.** 2b) ☒ *This action is non-final.*

3) ☐ *Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.*

Disposition of Claims

4) ☒ *Claim(s) 1-19, 21, 25, 26, 35-37, and 40-44 is/are pending in the application.*

4a) *Of the above, claim(s) _____ is/are withdrawn from consideration.*

5) ☐ *Claim(s) _____ is/are allowed.*

6) ☒ *Claim(s) 1-19, 21, 25, 26, 35-37, and 40-44 is/are rejected.*

7) ☐ *Claim(s) _____ is/are objected to.*

8) ☐ *Claims _____ are subject to restriction and/or election requirement.*

Application Papers

9) ☐ *The specification is objected to by the Examiner.*

10) ☐ *The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.*

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ *The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.*

If approved, corrected drawings are required in reply to this Office action.

12) ☐ *The oath or declaration is objected to by the Examiner.*

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ *Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).*

a) ☐ *All* b) ☐ *Some** c) ☐ *None of:*

1. ☐ *Certified copies of the priority documents have been received.*
2. ☐ *Certified copies of the priority documents have been received in Application No. _____ .*
3. ☐ *Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).*

**See the attached detailed Office action for a list of the certified copies not received.*

14) ☐ *Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).*

a) ☐ *The translation of the foreign language provisional application has been received.*

15) ☐ *Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.*

Attachment(s)

1) ☒ *Notice of References Cited (PTO-892)*
2) ☐ *Notice of Draftsperson's Patent Drawing Review (PTO-948)*
3) ☒ *Information Disclosure Statement(s) (PTO-1449) Paper No(s). 14*
4) ☐ *Interview Summary (PTO-413) Paper No(s). _____*
5) ☐ *Notice of Informal Patent Application (PTO-152)*
6) ☐ *Other:*

DETAILED ACTION

Continued Examination Under 37 CAR 1.114

1. A request for continued examination under 37 CAR 1.114, including the fee set forth in 37 CAR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CAR 1.114, and the fee set forth in 37 CAR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CAR 1.114. Applicant's submission filed on October 25, 2002 has been entered.

Specification

2. Claims 34,38, and 39 have been canceled without prejudice towards further prosecution. Claims 1 has been amended. New claims 42-44 have been added.

It is suggested to change the phrase, "enzymatic mediated" in claims 1 and 42 either to "enzyme mediated" or "enzymatic".

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4, 6, 8, 10-18, 25-26, 35 and 36-43 are rejected under 35 U.S.C. 103(a) over Nova et al. (U.S. Patent 6,100,026) (August 8, 2000) in view of Payne et al. (U.S. Patent 5,807,701) (September 15, 1998) further in view of Harris et al. (PCT International Publication Number WO 94/02634) (February 3, 1994).

Nova et al teach a method for monitoring information in a solid medium (Abstract), the medium comprising the steps of:

a) screening the medium with a screening means comprising a n number of sensing probes, where n is an integer of at least one so that more than one physical, chemical, or physico-chemical change which defines the information is detected by the probe to produce at least one signal output (Column 5, line 51 to Column 6, line 30, Column 25, line 66 to Column 26, line 4 and Column 79, lines 23 to column 89, line 30);

b) transferring the signal output to a signal processing means responsive to differences in electromagnetic properties of the signal for generating a final output (Column 6, lines 52-56, Column 12, lines 20-37 and Column 90, lines 27-54, Figure 7);

c) receiving the final output into a pattern recognition means sufficient to generate a measurement pattern of the information being operable to define a set of class boundaries (Column 7, line 64 to Column 8, line 18, Figures 24 and 31); and

d) sorting the information in accordance with the class boundaries representative of the presence and preferably quantitative amounts of biomolecule in the medium (Figure 31, Column 79, line 50 to Column 80, line 16 and Column 90, line 55 to column 91, line 53).

Nova et al teach a method wherein the n number of sensing probes is a multiple sensor array (Abstract and Column 87, line 31 to Column 89, line 31 and Column 7, lines 35-49).

Nova et al teach a method wherein the sensing probe comprises at least one conductive polymer sensor (Column 68, lines 28-38).

Nova et al teach a method wherein the sensing probe has a coating (Column 68, lines 28-38).

Nova et al teach a method wherein the sensing probe is an optical sensing probe (Abstract and Column 63, lines 30-62).

Nova et al teach a method wherein the sensing probe is an optical fiber (Column 63, line 63 to Column 64, line 18).

Nova et al teach a method wherein at least part of the information detected by the probe is changes in the concentration of the biomolecule (Column 79, line 50 to Column 80, line 16).

Nova et al teach a method wherein at least part of the information detected by the probe is changes in a secondary product of the biomolecule (Column 91, line 55 to Column 92, line 40).

Nova et al teach a method wherein at least part of the information detected by the probe is changes in a radiative property of the electromagnetic spectrum of the biomolecule (Column 6, lines 52-56, Column 12, lines 20-37 and Column 90, lines 27-54, Figure 7).

Nova et al teach a method wherein at least part of the information detected by the probe is changes in a non-radiative property of the electromagnetic spectrum of the biomolecule (Column 77, line 63 to Column 78, line 63).

Nova et al teach a method wherein at least part of the information detected by the probe is changes in a non-radiative property of the electromagnetic spectrum of a secondary product of the biomolecule (Column 91, line 55 to Column 92, line 40).

Nova et al teach a method wherein the medium comprises at least one of organic or inorganic solvent (Example 1).

Nova et al teach a method wherein the signal processing means comprises a frequency analyzer (Figure 24 and Column 81, lines 19-42).

Nova et al teach a method wherein the optical probe is an apertureless or apertured probe (Figure 8 and Column 55, line 44 to Column 56, line 23).

Nova et al teach a method wherein the medium is a mixture of amplification products and monitoring step monitors an amplification reaction (Column 13, lines 23-46).

Nova et al do not teach a method wherein the sensing probe is a semiconductor gas sensor.

Payne et al. teach a method wherein the sensing probe is a semiconductor gas sensor. (Abstract and Column 1, lines 45-49).

Nova et al do not teach a method wherein the information comprises at least one of volatile chemical species characteristic of the presence of the biomolecule or the part of the biomolecule.

Payne et al teach a method wherein the information comprises at least one of volatile chemical species characteristic of the presence of the biomolecule or the part of the biomolecule. (Figure 5).

Nova et al do not teach a method of reacting one or more volatile organic tags with the medium to attach to the biomolecules.

Payne et al. teach a method of reacting one or more volatile organic tags with the medium to attach to the biomolecules (Column 1, lines 56-60).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method of semiconductor gas sensor sensing probe of Payne et al. into the method of monitoring information of Nova et al. since Payne et al. state, "The invention comprises a method for identifying bacteria comprising detecting gas or vapor associated with the metabolic activity of the bacteria and differentiating such gas or vapor from gas or vapor associated with other bacteria (Column 1, lines 22-26)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the method of semiconductor gas sensor sensing probe of Payne et al. into the method of monitoring information of Nova et al. to improve the specific detection of bacteria. An ordinary practitioner would have been motivated to combine and substitute the method of semiconductor gas sensor

sensing probe of Payne et al. into the method of monitoring information of Nova et al. in order to achieve the express advantages noted by Payne et al., of an invention that comprises a method for identifying bacteria comprising detecting gas or vapor associated with the metabolic activity of the bacteria and differentiating such gas or vapor from gas or vapor associated with other bacteria.

Nova et al. in view of Payne et al do not teach a method for monitoring an enzyme mediated biomolecular reaction although Nova et al suggest nucleic acid amplification reaction can be monitored with that method (Column 13, lines 23-46).

Harris et al. teaches a method for monitoring an enzyme mediated biomolecular reaction (Abstract and Example 1 and Claims 1-25).

Nova et al. in view of Payne et al do not teach a method, wherein the enzyme mediated biomolecular reaction is a polymerase chain reaction selected from DNA templates and the polymerase is a Taq mediated PCR.

Harris et al. teaches a method, wherein the enzyme mediated biomolecular reaction is a polymerase chain reaction selected from DNA templates and/or RNA mixtures (Page 26 and abstract and Example 1 and Claims 1-25).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method for monitoring an enzyme mediated biomolecular reaction of Harris et al. into the method of monitoring information of Nova et al in view of Payne et al. since Harris et al. states, "This represents a major advance over prior art

systems. The system offers rapid detection with few manipulations and reduced risk of contamination of laboratories with amplicons (amplification products) compared to two vessel assays. The system thus facilitates processing of large number of diagnostic assays (Page 3, line 32 to page 4, line 4)." An ordinary artisan would have combined and substituted a method for monitoring an enzyme mediated biomolecular reaction of Harris et al. into the method of monitoring information of Nova et al in view of Payne et al. to improve the specific detection of amplification products. An ordinary practitioner would have been motivated to combine and substitute a method for monitoring an enzyme mediated biomolecular reaction of Harris et al. into the method of monitoring information of Nova et al in view of Payne et al. in order to achieve the express advantages noted by Harris et al., of an invention that represents a major advance over prior art systems and which offers rapid detection with few manipulations and reduced risk of contamination of laboratories with amplicons (amplification products) compared to two vessel assays, thus facilitating the processing of large number of diagnostic assays.

5. Claim 44 is rejected under 35 U.S.C. 103(a) over Nova et al. (U.S. Patent 6,100,026) (August 8, 2000) in view of Payne et al. (U.S. Patent 5,807,701) (September 15, 1998) further in view of Harris et al. (PCT International Publication Number WO 94/02634) (February 3, 1994) further in view of Takakura et al. (US 6,462,185 B1) (October 8, 2002) .

Nova et al. in view of Payne et al. further in view of Harris et al teach the method of claims 1-4, 6, 8, 10-18, 25-26, 35 and 36-43 as described above.

Nova et al. in view of Payne et al. further in view of Harris et al do not teach the method, wherein the polymerase is a Taq mediated PCR.

Takakura et al teach the method, wherein the polymerase is a Taq mediated PCR (Column 5, lines 49-55).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein the polymerase is a Taq mediated PCR of Takakura et al. into the method of monitoring information of Nova et al in view of Payne et al. further in view of Harris et al. since Takakura et al. states, "Also, the substitution, deletion, addition or insertion of specific nucleotide(s) may be conducted by the site-directed mutagenesis with the use of the PCR method or the random nucleotide substitution technique by taking advantage of the low fidelity of Taq DNA polymerase (Column 5, lines 49-55)." An ordinary practitioner would have been motivated to combine and substitute a method, wherein the polymerase is a Taq mediated PCR of Takakura et al. into the method of monitoring information of Nova et al in view of Payne et al. further in view of Harris et al. in order to achieve the express advantages noted by Takakura et al., of an invention by which the substitution, deletion, addition or insertion of specific nucleotide(s) may be conducted by the site-directed mutagenesis with the use of the PCR method or the random nucleotide substitution technique by taking advantage of the low fidelity of Taq DNA polymerase.

6. Claims 1-4, 6-18, 19, 21, 25-26, 35 and 36-41 are rejected under 35 U.S.C. 103(a) over Nova et al. (U.S. Patent 6,100,026) (August 8, 2000) in view of Payne et al. (U.S. Patent

5,807,701) (September 15, 1998) further in view of Harris et al. (PCT International Publication Number WO 94/02634) (February 3, 1994) further in view of Ashe et al. (U.S. Patent 5,699,270) (December 16,1997).

Nova et al. in view of Payne et al. further in view of Harris et al teach the method of claims 1-4, 6, 8, 10-18, 25-26, 35 and 36-43 as described above.

Nova et al in view of Payne et al. further in view of Harris et al. do not teach a method wherein the sensing probe is a resonant micromechanical device mass spectrometer.

Ashe et al. teach a method wherein the sensing probe is a resonant micromechanical device mass spectrometer (Abstract and Claim 3).

Nova et al in view of Payne et al. further in view of Harris et al do not teach a method wherein the multivariate analysis is principal component analysis, partial least squares and trained or untrained.

Ashe et al. teach a method wherein the multivariate analysis is principal component analysis, partial least squares and trained or untrained. (Abstract and Column 6, line 23 to Column 7, line 12).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method wherein the multivariate analysis is principal component analysis, deterministic finite-state automata, partial least squares and trained or untrained of Ashe et al. into the method of monitoring information of Nova et al. in view of Payne et al. further in view of Harris et al since, since Ash et al. state, "Coefficients

provided by this model are mathematically combined with the suitably treated mass spectral data from samples with unknown desired properties to: a) predict desired properties, b)assess the suitability of the model for such predictions, and c) diagnose the stability and general correctness of the process that yielded the mass spectral data (Column 7, lines 4-12)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the method wherein the multivariate analysis is principal component analysis, deterministic finite-state automata, partial least squares and trained or untrained of Ashe et al. into the method of monitoring information of Nova et al. in view of Payne et al. further in view of Harris et al. to improve the method of monitoring information of a biomolecule. An ordinary practitioner would have been motivated to combine and substitute the method wherein the multivariate analysis is principal component analysis, deterministic finite-state automata, partial least squares and trained or untrained of Ashe et al. into the method of monitoring information of Nova et al. in view of Payne et al. further in view of Harris et al. in order to achieve the express advantages noted by Ashe et al., of an invention that provides coefficients which are mathematically combined with the suitably treated mass spectral data from samples with unknown desired properties to: a) predict desired properties, b)assess the suitability of the model for such predictions, and c) diagnose the stability and general correctness of the process that yielded the mass spectral data.

7. Claims 1-6, 8, 10-18, 25-26, 35, and 36-41 are rejected under 35 U.S.C. 103(a) over Nova et al. (U.S. Patent 6,100,026) (August 8, 2000) in view of Payne et al. (U.S. Patent 5,807,701) (September 15, 1998) further in view of Harris et al. (PCT International Publication

Number WO 94/02634) (February 3, 1994) further in view of Ghahramani et al. (U.S. Patent 6,259,373 B1) (July 10, 2001).

Nova et al in view of Payne et al. further in view of Harris et al teach a method of claims 1-4, 6, 8, 10-18, 25-26, 35 and 36-43 as described above.

Nova et al in view of Payne et al. further in view of Harris et al do not teach a method wherein the medium is a gas or vapor, and wherein the sensing probe comprises at least one of a metal oxide gas sensor used in gas or vapor phase.

Ghahramani et al. teach a method wherein the medium is a gas or vapor, and wherein the sensing probe comprises at least one of a metal oxide gas sensor used in gas or vapor phase.(Column 24, lines 37-55).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method wherein the medium is a gas or vapor, and wherein the sensing probe comprises at least one of a metal oxide gas sensor used in gas or vapor phase. of Ghahramani et al. into the method of monitoring information of Nova et al. in view of Payne et al. further in view of Harris et al since Ghahramani et al. state, "The gas sensors must fulfill many exploitation requirements: the most important parameters are: sensitivity, selectivity, reading reproducibility, stability during the operation, quick response, small size safety operation, low power consumption, ~15 mW, and low cost (Column 24, lines 43-48)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the method wherein the medium is a gas or vapor, and wherein the sensing probe

comprises at least one of a metal oxide gas sensor used in gas or vapor phase. of Ghahramani et al. into the method of monitoring information of Nova et al. in view of Payne et al. further in view of Harris et al to improve the gas sensor probes. An ordinary practitioner would have been motivated to combine and substitute the method wherein the medium is a gas or vapor, and wherein the sensing probe comprises at least one of a metal oxide gas sensor used in gas or vapor phase. of Ghahramani et al. into the method of monitoring information of Nova et al. in view of Payne et al. further in view of Harris et al in order to achieve the express advantages noted by Ghahramani et al., of an invention that provides sensitivity, selectivity, reading reproducibility, stability during the operation, quick response, small size safety operation, low power consumption, ~15 mW, and low cost.

Response to Amendment

8. In response to amendment, previous 112 (second paragraph) and 103(a) rejections are hereby withdrawn. However, four new 103 (a) rejections are hereby included.

Response to Arguments

9. Applicant's arguments with respect to claims 1-19, 21, 25, 26, 35-37, and 40-44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703) 308-1152.Any inquiry of a general nature or relating to the status of this application should be directed tithe Group analyst Chantae Dessau whose telephone number is (703) 605-1237. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located In Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published In the Official Gazed OG 30 (November 15, 1989).

Arun Chakrabarti

Patent Examiner

Art Unit 1634

November 12, 2002

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